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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,696	10/28/2005	Shuji Ozaki	14875-141US1 C1-A0220P-US	1270
26161	7590	06/08/2009	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			GUSSOW, ANNE	
			ART UNIT	PAPER NUMBER
			1643	
			NOTIFICATION DATE	DELIVERY MODE
			06/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/530,696	Applicant(s) OZAKI ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 13-25, 28, 31-38 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 13-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 25, 28, 31-38 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 24, 31, 35, and 44 have been amended.

Claims 7-12, 26, 27, 29, 30, and 39-41 have been cancelled.

Claims 1-6 and 13-23 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 16, 2006.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 17, 2009 was filed after the mailing date of the first action on the merits on December 21, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

Rejections Withdrawn

3. The rejection of claims 24, 25, 27-29, 33 and 34 under 35 U.S.C. 102(b) as being anticipated by Woodle, et al. is withdrawn in view of applicant's amendment to the claims.

4. The rejection of claims 24, 25, 27-38, and 40-45 under 35 U.S.C. 103(a) as being obvious over Woodle, et al. in view of Ghetie, et al. is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claims 24, 25, 27-38, and 40-45 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is maintained.

Applicant's response filed February 17, 2009 has been carefully considered by the examiner but is deemed not to be persuasive. The response states that applicants note that this rejection hinges in part on the Office's incorrect interpretation of "cytotoxic activity." The Office Action appears to assume that cytotoxic activity means only apoptosis. This is not correct. The term "cytotoxic activity" is used in the claims and the specification to cover not only a cell death-inducing activity such as apoptosis, but also a cell growth-suppressing activity. Applicants draw the Examiner's attention to dependent claims 34 and 43 of this application, which further limit the "cytotoxic activity" of independent claims 24 and 35, respectively, to be a "cell growth-suppressing activity." Note also the disclosure at page 30, line 20, to page 31, line 3, of the application as filed. This section of the application clearly indicates that cytotoxicity does not necessarily require apoptosis, because the exemplified embodiment, 2D7DB, induces cytotoxicity by a non-apoptotic mechanism. When the application and the pending claims are properly understood, Genestier and the other Examiner- cited art

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actually support Applicants' compliance with the written description requirement (see response pages 8-9).

In response to this argument, the examiner agrees with applicant's interpretation of the term "cytotoxicity". When given the broadest reasonable interpretation in view of the specification cytotoxicity reads on any effect to the cell that reduces cell growth or induces cell death. Genestier, et al. uses apoptosis as their measurement of cytotoxicity and teaches that the antibodies have different effects when binding to the same antigen. Genestier, et al. teach that the same antibodies had varying effects on cellular proliferation (table 2 and figure 1). Thus, the Genestier, et al. citation supports the position of a minibody having different cytotoxic effects when compared to a full length antibody.

Regarding applicant's arguments in view of the related court cases (see response pages 9-11), the issue here is not the antigen bound by the antibody, but rather the structure of the antibody with increased cytotoxic activity. Applicant is claiming a method of producing a minibody which binds to a known antigen. The specification defines a minibody as an antibody that lacks a portion of a whole antibody (page 5 lines 19-20). Therefore, the broad genus contains hundreds if not thousands of possible antibody structures that are not a whole antibody. Genestier, et al. teach Fab' and F(ab')₂ antibody fragments (this minibodies) which do not have increased cytotoxic activity compared to the full length antibody (figure 4).

Thus only the 2D7 antibody meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant's 2D7 antibody does is not representative of the genus given the data of Genestier, et al. which support not all HLA class I antibodies have

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cytotoxic activity and the instant disclosure does not characterize or identify the epitope or structure connected with the cytotoxic activity.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
June 2, 2009

/Anne M Gussow/
Examiner, Art Unit 1643

/David J Blanchard/
Primary Examiner, Art Unit 1643